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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,647	07/28/2000	Yves Fouillet	GENSET.077AUS	2266

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1634

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17

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/627,647	FOUILLET ET AL.	
	<b>Examiner</b> Bradley L. Sisson	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 November 2002.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 13-51 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12 and 52-71 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 13-51 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

### ***Specification***

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 10, 11, 54-62, 64, 65, and 69 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kopp et al.

5. Kopp et al., discloses a device for performing continuous-flow PCR wherein the sample is passed along a channel under pressure and is caused to undergo thermal cycling while flowing. As seen in Fig. 1, the device comprises an inlet basin, and outlet basin as well as fluid communication means whereby reagents can be added (Fig. 1B).

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6. The device is manufactured in a glass chip; see abstract. Such a teaching meets the limitation that “the substrate consists essentially of silicon;” a limitation of claims 10 and 64.

7. Figure 2A depicts results that were detected subsequent to performing the amplification reaction. Such a showing is considered to meet the limitation that the device further comprises a detector for measuring a physicochemical property of a biological sample; a limitation of claims 11 and 65. As seen in Fig. 2A, the sample can be evaluated not only for the presence or absence of specific nucleic acid sequences, but for their size, relative concentrations, etc.

8. The aspect of being capable of cycling between temperatures is considered to be met by the availability of one to simply turn off the device as is afforded by digital temperature controllers and switching electronics. Aside from simply turning off the device so to effect temperature cycling, the device also has the capacity to “cycle” between temperatures as a result of the control mechanism, e.g., the set points at which heating commences and stops. The stopping of heating will ultimately result in cooling. Again, the level at which the device is programmed to renew heating speaks of there being temperature cycling between upper and lower thresholds. It is further noted that the claims do not specify any specific limits over which the temperature is to range.

*Response to arguments*

9. At pages 2-3 of the response received 19 November 2002, hereinafter the response, applicant asserts that a proper rejection has not been set forth in that Kopp et al., does not disclose a device capable of cycling between at least two temperatures.

10. The above argument has been fully considered and has not been found persuasive. It is noted with particularity that the claims do not recite over what range the temperature is to cycle

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or what means are to be employed so to affect such cyclization. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-12, 54-66, and 69-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Mastrangelo et al.

13. Mastrangelo et al., column 8, disclose a microfluidic device comprising at least one temperature regulated zone which is capable of cycling between at least two temperatures, and is also adapted to bring at least a portion of aid sample pathway to said temperatures while a sample is continuously flowing along said pathway. As set forth in the first and third paragraphs, the temperature cycling portion of the sample pathway also serves as a thermal pump. Said thermal pump undergoes cycling of temperature so as to cause a thermal gradient (applicant's at least two temperatures) an herby cause the fluid (applicant's sample) to flow or move in the sample channels. As seen in the figures, the device can comprise a series of channels in parallel as well as sample reservoirs and basins.

14. The aspect of the device comprising two thermally regulated zones (claim 52) is considered to be met by the prior art in that one such zone can comprise the temperature cycling

means and the other, fixed temperature, can be a region upstream from the pump which is not heated at all but remains at a constant (ambient) temperature.

15. A limitation of claim 54 is met by the prior art in that Mastrangelo et al., teaches that a plurality of such thermocompression pumps can be used. Accordingly, the invention of claims 1-6, 10, 11, 54-62, 64, 65, and 69 is anticipated by the prior art of record.

***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 7-9, 63, 67, 68, 70, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopp et al., in view of Wilding et al. (US Patent 5,498,392). Kopp et al., teach that multiple samples can be present in one channel and that they are separated by a separator comprising buffer; see page 1047, right column first paragraph.

20. See above for the basis of the rejection as it pertains to the disclosure of Kopp et al.

21. Kopp et al., does not disclose their device as having a plurality of pathways, or that the device comprises one temperature regulated zone that is capable of cycling between at least two temperatures; or that the channels are arranged in parallel and that they are rectilinear.

22. Wilding et al., (US Patent 5,498,392) disclose a device for performing PCR wherein channels are manufactured in a silicon or glass chip. As seen in Fig. 2, at least a portion of the channel means are rectilinear. In Fig. 13 one can see that there are a plurality of pathways and that they are arranged in parallel.

23. Wilding et al., column 9, teach explicitly of the device comprising heating and cooling means. Such means is considered to meet the limitation that the device can heat and cool a given region. At column 10, the aspect of having the fluid flow continuously between two regions so “to implement continual polymerase chain reaction cycle” is disclosed.

24. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the device of Wilding et al., with that of Kopp et al., so to allow for the processing of multiple samples simultaneously. While Kopp et al., teach via their Fig. 1 that

the channel is arranged in parallel, the disclosure of Wilding et al., provides adequate motivation for having multiple channels in parallel arrangement, thereby allowing one to take advantage of the economy of scale. In view of the well-developed nature of the art and the detailed description provided, the ordinary artisan would have been both well motivated and would have had a reasonable expectation of success.

Response to argument

25. At pages 4-6 of the response applicant asserts that one would not be motivated to have combined the teachings of Wilder et al., with that of Kopp et al., as Kopp et al., discloses continuous flow while Wilding et al., discloses batch processing and he sue of a single amplification chamber.

26. The above arguments have been fully considered and have not been found persuasive towards the withdrawal of the rejection. Agreement is reached in that Kopp et al., disclose continuous flow of a fluid that can undergo thermal cycling. It is note with particularity that Wilding et al., disclosed a multitude of embodiments. While one such embodiment is that of a single chamber, Wilding et al., column 10, also discloses continuous flow of a sample:

The pump **52**, which also may be controlled by a microprocessor in the appliance, is then used to cycle the sample continuously between sections **22A** and **22B**, through channel **20B** to implement a continual polymerase chain reaction cycle, while port **16B** serves as a vent. (Emphasis added.)

27. In view of such explicit guidance as to performing continuous flow of a sample and its undergoing thermal cycling, one or ordinary skill in the art would have been motivated to have combined the teachings of Wilding et al., with that of Kopp et al.

28. Acknowledgement is made of applicant having asserted secondary considerations such as “advantages over the prior art,” *i.e.*, “use of a temperature regulated zone which is capable of cycling between at least two temperatures” which means “very little surface area is required per pathway” (response at page 5).

This argument has been fully considered as the claims do not recite any limitations as to surface area used or not used, closeness of one channel to that of another. In short, applicant is arguing limitations not to be found in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

29. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

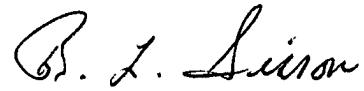
### ***Conclusion***

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

31. If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

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32. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson

Primary Examiner

Art Unit 1634

BLS

January 26, 2003